Johari Digital Healthcare Ltd.

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ISO 9001Certified

Special 510(k)

ANNEXURE 'VIII'

SUMMARY

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"Special 510(k) Summary"

Submitter's name	:	**JOHARI DIGITAL HEALTHCARE LTD.**
Address	:	**EC-1-2-3, Electronics Complex** **Light Industrial Area** **Jodhpur - 342003 INDIA**
Phone	:	**+91-291-741183**
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E-mail	:	**joharicare@sify.com**
Contact Person	:	**Nisha Johari**
Date of Summary is submitted	:	**27.11.2002**
Resubmitting on	:	**N.A.**

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Special 510(k) **ANNEXURE 'VIII'**

MODIFIED DEVICE FOR WHICH SUBMITTING

Trade Name	:	**Combo Stimulator IF-5000**
Common Name	:	**Electrical Nerve & Muscle Stimulator**
Classification Name	:	**Physical Medicine (Per 21 CFR Section 890) and Neurology (Per 21 CFR Section 882-5890).**

LEGALLY MARKETED DEVICE

Analgesic Pulsar AP-439	:	**Nerve & Interferential Stimulator** 510(k) Number **K993229**
Manufacturer	:	**JOHARI DIGITAL HEALTHCARE LTD.**
Address	:	**EC-1-2-3, ELECTRONIC COMPLEX, LIGHT INDUSTRIAL AREA, JODHPUR – 342 003 INDIA**
Tel.	:	**+91-291-2741183**

DESCRIPTION OF MODIFIED DEVICE IF-5000

Johari **'Combo Stimulator'** is a Neuromuscular Electrical Stimulation System, consists of programmable controller just like the predicate device Analgesic Pulsar AP-439. This unit Combo Stimulator allows the treatment specifically tailored to the precise needs of the patient in the clinic and for subsequent treatment off site. The clinicians can set the treatment parameters and lock it, so patient can repeatedly use the unit as prescribed by the clinician. The stimulation is most comfortable and the waveforms are unique.

It has been the clinician requirement many a times where they wanted to have a unit that can perform for muscle stimulation followed by interferential, so that, the painful muscle condition can be treated. Usually they have to turn the machine On and Off for different stimulation waveforms. The unique feature of Combo Stimulator is that in such above conditions, the clinicians can set the unit to perform in such a way that desired muscle stimulation can be followed by desired Interferential stimulation just by pressing one key "Combo", otherwise in itself the unit can perform muscle stimulation through all the outputs or Interferential stimulation through all the output.

The ease and simplicity by which the programming can be done is not more than touch of the key on the panel and LCD display. All the parameters remain in the system control except the amplitude & time which can be set by the patient himself. This unit is ergonomically designed, so that, it is comfortable to hold in hands.

It is portable and has two output channels, four channels works on rechargeable battery system. The unit can perform offsite wherein the hospital room, clinic or home while the predict device Analgesic Pulsar could not run on rechargeable battery system and so limited its use near to the AC outlet. This has always limited the clinicians to perform on their patient. Also many times, the patient may be in need to have a repeated treatment and this modified device "Combo Stimulator" can work in such cases. The Combo Stimulator can provide True Interferential with desired frequency, sweep selection and muscle stimulation of desired mode similar to Analgesic Pulsar.

Combo Stimulator IF-5000 comes complete with all the necessary components to perform Pain Relief & Electrical Stimulation. Below is a list of items that are included:

1.	Combo Stimulator IF-5000 unit	01
2.	Electrode Cable (4 Core)	02
3.	Electrode 2.75" Round Diameter(Self Adhesive)	08
4.	Adapter	01
5.	Rechargeable batteries	04
5.	Manual	01
6.	Carry Bag	01

The only difference in these two devices is that:

a) Predicate Device AP-439 is a bigger in size.

b) Predicate Device AP-439 uses direct AC mains whereas Combo Stimulator IF-5000 uses rechargeable battery system and makes it much more safe and effective.

c) Both the units have two outputs with four channels (8 electrodes).

d) Both are Micro-computer controlled and digital displays guide through the programming.

e) Both are ABS molded ergonomically designed but since IF-5000 is small in size, which can be used repeatedly and at home also.

INTENDED USE OF MODIFIED DEVICE IF-5000

Modified unit "Combo IF 5000" has similar intended use as predicate device **Analgesic Pulsar AP-439**. Both the electrical stimulators are to be used in Physical Medicine by Clinicians and Therapists.

INTENDED USE

A) **Interferential Current Stimulation** is indicated for :

1. Symptomatic relief and management of chronic and intractable pain.
2. Adjunctive treatment in the management of post-surgical and post-traumatic, acute pain conditions.

B) **Electrical Muscle Stimulation (EMS or Russian)** is indicated for:

1. Relaxation of Muscle spasm.
2. Prevention or Retardation of disuse atrophy.
3. Increasing local blood circulation.
4. Muscle re-education.
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
6. Maintaining or increasing range of motion.

INTENDED USE OF ANALGESIC PULSAR AP-439

(A) Interferential current stimulation , Premodulated Bipolar Mode and Faradic Stimulation is indicated for :

1. Symptomatic relief and management of chronic, intractable pain.
2. Adjunctive treatment in the management of post-surgical and post-traumatic, acute pain conditions.

(B) **Electrical Muscle Stimulation (Russian and Galvanic-interrupted) is indicated for:**

1. Relaxation of Muscle spasm.
2. Prevention or Retardation of disuse atrophy.
3. Increasing local blood circulation.
4. Muscle re-education.
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
6. Maintaining or increasing range of motion.

(C) Galvanic-DC Continuous mode is indicated for:-

1. Relaxation of muscle spasm.

TECHNICAL SPECIFICATIONS OF THE MODIFIED DEVICE IF-5000

IF-5000 has basically same Technical Specification as predicate Analgesic Pulsar AP-439.

Power Source	: 1.2V x 4 Ni-Mh Rechargeable batteries
Number of outputs	: Two
Channels	: Four
Synchronous	: Yes
Max out put current	: Select PW & Ramp Burst – 90mA pp @ 500 ohm load Russian & IFT – 54mA RMS @ 500 Ohm Load
Max out put voltage	Select PW & Ramp Burst – 90mA vpp @ 10K ohm load Russian & IFT – 37V RMS @ 10k Ohm Load
Channel isolation	: Yes, confirm to ANSI 3.2.3.2, 1985.
Waveform	: Biphasic & Sinewave
Current density on 2" diameter electrodes	Select PW & Ramp Burst – 0.533 mA/cm2 @ 500 ohm Russian & IFT – 2.66mA/cm2 @ 500 Ohm
Power density On 2" diameter electrodes	Select PW & Ramp Burst – 0.024 W/cm2 @ 500 ohm Russian & IFT – 0.072 W/cm2 @ 500 Ohm
Max. phase charge	Select PW & Ramp Burst
at 500 Ohm	18 micro coulomb
at 2 K Ohm	7.4 micro coulomb
at 10 K Ohm	1.8 micro coulomb
	Russian
at 500 Ohm	5.4 micro coulomb
at 2 K Ohm	1.7 micro coulomb
at 10 K Ohm	0.37 micro coulomb
	IFT
at 500 Ohm	2.7 micro coulomb
at 2 K Ohm	0.85 micro coulomb
at 10 K Ohm	0.18 micro coulomb
Modulation Options	
Amplitude	Preset IFT & Russian only
Frequency	IFT section only
Mechanical Specifications	Weight 1 Lb, Size: 3.9"(l) x 1.6"(h) x 4.0(d)
Pulse Width	Selectable PW: 50 to 400 μs in step of 50 Ramp Burst: 400 μs Russian: 200 μs IFT: 100 μs

TECHNICAL SPECIFICATIONS OF THE PREDICATE DEVICE DEVICE ANALGESIC PULSER AP-439

Power Source	: 110V AC, 50/60 Hz.
Number of outputs	: Two
Channels	: Four
Synchronous	: Yes
Max out put current	: 100mA (max. @ 500 ohm loads)
Max out put voltage	132V pp (max. @ 10K ohm loads)
Channel isolation	: Yes, confirm to ANSI 3.2.3.2 , 1985.
Waveform	: Monophasic, Biphasic, Sinewave & D.C. Line
Current density on 2" diameter electrodes	: 3.55mA/cm2 (max @ 500 ohm load)
Power density on 2" diameter electrodes	: 0.127 W/cm2 (max @ 500 ohm load)
Max. phase charge	: 40 micro coulomb (max @ 500 ohms load)

Modulation Options

Amplitude	: Preset IFT only
Frequency	: IFT section only
Mechanical Specifications	: Weight 5.5 Lb, 12.2" (l)X 3.5" (h)X 7.5" (d)
Pulse width	: Faradic: 100-400 (selectable) IFT: 125 µs. phase interval Russian: 200 µs Galvanic: D.C.

TECHNOLOGICAL CHARACTERISTICS

1. **MICRO-CONTROLLER**
Combo Stimulator IF-5000 & Predicate device Analgesic Pulsar AP-439 both the units are programmable Microcomputer Controlled. HMOS Micro-controller is used in IF-5000, which makes it reliable with Electro Magnetic Compatibility while in AP-439, Microcontroller 87C51 is used on a base of oscillating crystal at frequency 12M Hz.

2. **MULTICHANNEL**
Combo Stimulator IF-5000 & Predicate device AP-439 both the units have two outputs (four channels – eight electrodes) to provide different kind of stimulation to body sites.

3. **MULTIWAVE SELECTIONS & PROGRAMABILITY**
Combo Stimulator IF-5000 produces selection of Muscle Stimulation (selectable pulse width mode, ramp burst & Russian 2500 Hz.) & Interferential Stimulation (frequency of 5000 Hz with three fixed sweep frequencies and one fixed beat frequency.) for pain relief through all the outputs. If desired, the clinicians can select the Combination Stimulation, which combines EMS (for 1 minute and more) and IFT (for 1 minute and more) throughout the treatment session.
Predicate device AP-439 produces selection of Interferential (4000 Hz.–Vector & Premod with programmable sweep frequency), Russian (2500 Hz), Galvanic & Faradic (6 preset programs with selectable pulse width and pulse rate).

4. **DISPLAY**
Combo Stimulator IF-5000 has LCD (Liquid Crystal Display) for showing Treatment Mode, Contraction period, Relaxation period, Treatment Time and Intensity in both the outputs.
Predicate device AP-439 has LED display to show Percentage Power, Cyclic On /Off Time, Treatment Time and balance Treatment Time.

5. **POWER**
Combo Stimulator IF-5000 works on rechargeable battery back up, so the treatment will not be limited to site near AC outlet and can be carried along. This makes the unit further safe. While Predicate device Analgesic Pulsar AP-439 works on 110V 60Hz AC mains only.

6. **TACTILE TOUCH CONTROL**
Both the units are beautifully designed with the Membrane Panel, provides easy touch entry for treatment selection. The audible note with each key entry ensures clinician that selection is made.

7. **CASING**
Both the units are attractive and fitted in an ABS body enclosure. They are strong and sturdy. IF-5000 is handy, smaller and more ergonomic design, so that can be held in hand while AP-439 is a desktop unit.

8. **WEIGHT**
Combo Stimulator IF-5000 - Weigh **1.0** Lb., Predicate device AP-439 - weigh **5.5** lb.

SAFETY:

1. From circuitry to output again there is an insulation through transformers, thereby provision of double separations between mains & the human body (where output is to be applied)

2. Membrane key boards are provided which are known to withstand operation of key pressing much more than other mechanical methods.

3. Circuitry efficacy is good as matrix circuitry is used in keyboard & amplification circuitry is simple.

4. In case failure of any IC or component, the intensity will automatically come down to zero in

5. IF-5000 & AP-439 can be carried along for easy use at home or clinics.

SUMMARY

Combo Stimulator IF-5000 is not designed to be worm by patient.

IF-5000 has a self-contained safety circuit.

Open/short circuit performance: This IF-5000 functions normally after open and short circuited conditions between output jacks, with the device operating for maximum of 15 minutes, in each condition at the maximum available setting of pulse width, pulse rate and pulse amplitude.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Nisha Johari
Johari Digital Healthcare Ltd.
Vandana, 28 Nehru Park
Jodhpur – 342003, India

Re: K024036
Trade/Device Name: Combo Stimulator IF-5000
Regulation Number: 21 CFR 890.5850 and unclassified
Regulation Name: Powered Electrical Muscle Stimulator and Interferential Current Electrical Stimulator
Regulatory Class: Class II
Product Code: IPF and LIH
Dated: November 27, 2002
Received: December 6, 2002

Dear Mrs. Johari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Combo Stimulator IF-5000 provides combination of desired stimulating currents, which can be chosen by clinicians for the following treatment therapies:

INTENDED USE

(A) **Interferential Current Stimulation** is indicated for:

1. Symptomatic relief and management of chronic, intractable pain.
2. Adjunctive treatment in the management of post-surgical and post-traumatic, acute pain conditions.

(B) **Electrical Muscle Stimulation (EMS or Russian)** is indicated for:

1. Relaxation of Muscle spasm.
2. Prevention or Retardation of disuse atrophy.
3. Increasing local blood circulation.
4. Muscle re-education.
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
6. Maintaining or increasing range of motion.

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K024036